Exhibit 3

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200 Park Avenue, 17th Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

FDA FREEDOM OF INFORMATION ACT APPEAL
EXPEDITED PROCESSING

VIA EMAIL June 1, 2022

Director, Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
FDAFOIA@fda.hhs.gov

Re: ***Expedited Processing Appeal of FOIA Control #2022-1614 (IR#0710)***

Dear Sir or Madam:

This firm represents Public Health and Medical Professionals for Transparency ("**PHMPT**"). On behalf of PHMPT, on February 23, 2022, we requested records on an expedited basis from the files of the Food and Drug Administration ("**FDA**") pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**"). The FDA designated the request as FOIA Control #2022-1614 (the "**FOIA Request**"). In a letter dated March 7, 2022, the FDA denied PHMPT's request for expedited processing (the "**Denial Letter**"). PHMPT writes now to appeal that determination.

A. The FOIA Request

On February 23, 2022, PHMPT submitted the FOIA Request to the FDA for the following documents:

> All data and information for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e)[1] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

[1] 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . (4) A list of all active ingredients and any inactive ingredients . . . . (5) An assay method or other analytical method . . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . . (7) All records showing the manufacturer's testing of a particular lot . . . . (8) All records showing the testing of and action on a particular lot by the [FDA]."

(**Exhibit 1**.)[2]

In the FOIA Request, PHMPT requested that the FDA expedite processing for this request pursuant to 5 U.S.C. § 552(a)(6)(E)(v)(II) and provided detailed reasons for requesting expedited processing. (**Exhibit 1**.)

On March 1, 2022, FDA acknowledged the FOIA Request and assigned it Request Number #2022-1614. On March 7, 2022, FDA and denied PHMPT's request for expedited processing. (**Exhibit 2**.) The denial letter stated in relevant part:

> The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."
>
> I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing. The responding agency office will process your request in the order in which it was received.

(**Exhibit 3**).

B. Argument

FOIA provides for "expedited processing of requests for records" upon a showing of "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). A requestor shows a "compelling need" when it is "primarily engaged in disseminating information," and there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II).

PHMPT requested expedited processing of the FOIA Request on the basis that it is "primarily engaged in disseminating information" and that there is an "urgency to inform the public concerning actual or alleged Federal Government activity." PHMPT demonstrated in its FOIA Request that it exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines. (**Exhibit 1**.) That

[2] All "Exhibits" referenced herein are appended to this letter.

fact was not challenged by the FDA in its Denial Letter and, therefore, this appeal, focuses solely on the FDA's claim that PHMPT failed to demonstrate "there exists an urgency to inform the public concerning actual or alleged Federal Government activity." (**Exhibit 3.**) For the purposes of this appeal PHMPT fully incorporates all of the arguments, references, and citations exhaustively detailed in its FOIA Request for expedited processing.

Contrary to FDA's assertions, as set forth in PHMPT's FOIA Request, there exists an urgency to inform the public concerning actual or alleged Federal Government activities. In determining whether there is an "urgency to inform," and hence a "compelling need," courts must consider at least three factors: (i) whether the request concerns a matter of current exigency to the American public; (ii) whether the consequences of delaying a response would compromise a significant recognized interest; and (iii) whether the request concerns federal government activity. *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001). All three factors are present here and weigh in favor of granting expedited processing of PHMPT's FOIA Request.

(i) PHMPT's request concerns a matter of current exigency to the American public

As to the first factor, PHMPT's FOIA Request concerns a matter of current exigency to the American public. PHMPT's FOIA Request is for the Moderna Vaccine's biological product file, available under 21 C.F.R. § 601.51(e). The FDA itself acknowledges the exigency in releasing the biological product file in the Code of Federal Regulations, which expressly provides that "[a]fter a license has been issued . . . data and information in the biological product file are *immediately available for public disclosure* unless extraordinary circumstances are shown." 21 C.F.R. § 601.51(e) (emphasis added). Under this regulation, a critical part of the biological product file that must be released is "all safety and effectiveness data and information." 21 C.F.R. § 601.51(e)(1). Therefore, the FDA's own regulations acknowledge the current exigency in making the Moderna Vaccine's biological product file, including its safety and effectiveness data and information, immediately available for public disclosure. Thus, FDA's regulation not only supports the need for expedited treatment under FOIA, but it is also an independent legal basis that requires expedited treatment of the FOIA Request.

Beyond the FDA's own regulations recognizing the exigency of records sought in PHMPT's FOIA request, there are other reasons why such exigencies exist. As required by Congress, the FDA may only license vaccines that have been proven to be "safe and effective," *see, e.g.*, 21 U.S.C. § 393. The FDA makes this determination based on, *inter alia*, clinical trial reports provided by the sponsor which must be sufficient to demonstrate the product is both "safe" and "effective."[3] 21 C.F.R. 601.2(a). There is, however, an ongoing public national debate regarding the adequacy of the data, information, and analyses relied upon by the FDA to license the Moderna Vaccine. On the one hand, there are numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and information underlying the licensure of the Moderna Vaccine

[3] The FDA explains in its guidance materials that the clinical trials relied upon for approval are typically "1 to 4 years" (https://www.fda.gov/patients/drug-development-process/step-3-clinical-research) and the duration of clinical trials should "reflect the product and target condition." https://www.fda.gov/media/102332/download (last visited 02/19/2022). *See also* https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved (last visited 02/19/2022); https://www.fda.gov/about-fda/what-we-do (last visited 02/19/2022).

is more than sufficient for licensure. For example, in a statement released on January 31, 2022, then-acting FDA Commissioner Janet Woodcock, M.D., stated:

> The public can be assured that Spikevax meets the FDA's high standards for safety, effectiveness and manufacturing quality required of any vaccine approved for use in the United States. While hundreds of millions of doses of Moderna COVID-19 Vaccine have been administered to individuals under emergency use authorization, we understand that for some individuals, FDA approval of this vaccine may instill additional confidence in making the decision to get vaccinated.[4]

Peter Marks, M.D., Ph.D., the director of FDA's Center for Biologics Evaluation and Research, made similar remarks:

> The FDA's medical and scientific experts conducted a thorough evaluation of the scientific data and information included in the application pertaining to the safety, effectiveness, and manufacturing quality of Spikevax. This includes the agency's independent verification of analyses submitted by the company, our own analyses of the data, along with a detailed assessment of the manufacturing processes, test methods and manufacturing facilities . . . Safe and effective vaccines are our best defense against the COVID-19 pandemic, including currently circulating variants. The public can be assured that this vaccine was approved in keeping with the FDA's rigorous scientific standards.[5]

Even prior to FDA approval of the Moderna Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines were "safe and effective."[6]

On the other hand, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, the adequacy of the review, and the appropriateness of the analyses relied upon to license the Moderna Vaccine, including a number of scientists and journalists who are members of PHMPT. For example, in July 2021, a group of 27 clinicians, scientists, and patient advocates, including PHMPT members Peter Doshi, Ph.D., Senior Editor for The BMJ and Associate Professor of Pharmaceutical Health Services Research at the University of Maryland School of Pharmacy,[7] and Peter A. McCullough, M.D. filed an amended Citizen Petition[8] with the FDA, claiming that the available evidence for licensure

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[4] https://www.cnn.com/2022/01/31/health/moderna-covid-vaccine-fda-approval/index.html (last visited 03/16/22).

[5] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine (last visited 03/16/22).

[6] *See, e.g.*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=COVID%2D19%20vaccines%20are%20safe,vaccine%20as%20soon%20as%20possible. (last visited 02/19/2022). *See also* https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection ("COVID-19 vaccines have proven to be safe, effective and life-saving.") (last visited 02/19/2022); https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/SafetyandEffectiveness ("COVID-19 vaccines are safe") (last visited 02/19/2022).

[7] https://www.bmj.com/about-bmj/editorial-staff/peter-doshi (last visited 02/19/2022).

[8] https://www.regulations.gov/document/FDA-2021-P-0521-0001 (last visited 02/19/2022).

of the Moderna Vaccine "is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations."[9] Separately, Dr. Doshi has publicly questioned the lack of transparency regarding the vaccine approval process[10] which Dr. Peter Marks publicly disputed.[11] Aaron Kheriaty, M.D., former-Professor of Psychiatry at UCI School of Medicine, former-Director of the Medical Ethics Program at UCI Health,[12] and a member of PHMPT, has also questioned the FDA's approval process. For example, in an article published in the Wall Street Journal, Dr. Kheriaty questioned the need for student vaccination requirements based on, among other things, a review[13] by the FDA's Vaccines and Related Biological Products Advisory Committee that indicates a risk of heart inflammation after vaccination.[14] Government officials have raised similar concerns about the lack of transparency in the review process, arguing that it is "essential" for the FDA to, among other things, "make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public."[15] PHMPT incorporates by reference, as if cited and fully set forth herein, any and all articles, media, and publications regarding or reflecting the public discussion, discourse, and debate regarding the Moderna Vaccine, including all matters related to the licensure of this product.

Given this widespread and ongoing public debate, the medical and scientific communities and the public have an immediate need to review the data and information underlying the licensure of the Moderna Vaccine. The FOIA Request attempts to expedite the disclosure of this critical information. Therefore, PHMPT's FOIA Request concerns a matter of current exigency to the American public.

Secondly, this public debate over the safety and effectiveness of the Moderna Vaccine concerns matters of current exigency to the American public because it has led to invasive policy decisions that affect the livelihoods of the American public. Over the objections of many, this product is being mandated to individuals across the country by the federal government,[16] local

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[9] *See* https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/ (last visited 02/19/2022).

[10] *See* https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (last visited 2/19/2022); https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-Pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/ (last visited 2/19/2022); https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-Pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/ (last visited 02/19/2022).

[11] https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-Pfizer-biontech-vaccine/ (last visited 02/19/2022).

[12] https://www.aaronkheriaty.com/bio (last visited 02/19/2022).

[13] https://www.fda.gov/media/150054/download (last visited 02/19/2022).

[14] https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (last visited 02/19/2022).

[15] https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf (last visited 02/19/2022).

[16] *See, e.g.*, https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1 (last visited 02/19/2022); https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c (last visited 02/19/2022); https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF (last visited 2/19/2022);

governments,[17] public and private employers,[18] universities,[19] schools,[20] and various other institutions,[21] and many others are expected to follow suit. At the federal level, legislation was introduced that would require COVID-19 vaccines for air travel into or out of the United States,[22] and the Pentagon has mandated COVID-19 vaccines for all military personnel.[23] At the state level, legislation has been introduced to require COVID-19 vaccines for all post-secondary students,[24]

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https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/fact-sheet-president-biden-to-announce-new-actions-to-get-more-americans-vaccinated-and-slow-the-spread-of-the-delta-variant/ (last visited 02/19/2022).

[17] *See, e.g.*, https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html (last visited 02/19/2022); https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page (last visited 2/19/2022); https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html (last visited 02/19/2022).

[18] *See, e.g.*, https://www.cnbc.com/2021/08/06/united-airlines-vaccine-mandate-employees.html (last visited 02/19/2022); https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/ (last visited 2/19/2022); https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220 (last visited 02/19/2022); https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/ (last visited 02/19/2022); https://www.cnbc.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html (last visited 2/19/2022); https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/ (last visited 02/19/2022); https://thehill.com/policy/healthcare/569051-Pfizers-full-approval-triggers-new-vaccine-mandates (last visited 02/19/2022); https://cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees (last visited 02/19/2022).

[19] *See e.g.*, https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916 (last visited 02/19/2022); https://www.colorado.edu/covid-19-updates/covid-19-vaccination (last visited 02/19/2022); https://uhs.berkeley.edu/requirements/covid19 (last visited 02/19/2022); https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs (last visited 02/19/2022); https://www2.gmu.edu/safe-return-campus/vaccination-requirements (last visited 2/07/2022).

[20] *See, e.g.*, https://www.npr.org/sections/back-to-school-live-updates/2021/08/20/1029837338/a-california-school-district-mandates-vaccines-for-eligible-students (last visited 2/19/2022); https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band (last visited 2/19/2022); https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/ (last visited 02/19/2022); https://www.nj.com/hudson/2021/08/hoboken-believed-to-be-first-in-state-to-issue-mandate-for-students-12-and-up-get-vaccine-or-face-weekly-testing.html (last visited 02/19/2022); https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/ (last visited 02/19/2022).

[21] *See, e.g.*, https://www.reuters.com/world/us/new-york-city-mandates-covid-19-vaccine-public-school-teachers-staff-mayor-2021-08-23/ (last visited 02/19/2022); https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/ (last visited 02/19/2022); https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html (last visited 02/19/2022); https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers (last visited 02/19/2022); https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx (last visited 02/19/2022); https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html (last visited 02/19/2022); https://www.denvergov.org/Government/COVID-19-Information/Public-Health-Orders-Response/News-Updates/2021/Mayor-Hancock-Announces-COVID-19-Vaccine-Requirement-for-Employees (last visited 2/19/2022); https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/ (last visited 02/19/2022).

[22] https://www.congress.gov/bill/117th-congress/house-bill/4980?q=%7B%22search%22:%5b%224980%252 (last visited 02/19/2022).

[23] https://thehill.com/policy/defense/568996-pentagon-to-mandate-covid-19-vaccine-for-military (last visited 02/19/2022).

[24] *See* New York bill S6495, available at https://www.nysenate.gov/legislation/bills/2021/S6495 (last visited 02/19/2022).

all state employees, [25] and even for all citizens of several states.[26] As explained by Dr. Anthony Fauci, "a flood" of vaccine mandates follow FDA approval of a COVID-19 vaccine,[27] and President Biden has actively encouraged "companies in the private sector to step up the vaccine requirements[.]"[28]

During a time when COVID-19 vaccine mandates are being implemented over the objection of those that have questions about the data and information supporting the safety and efficacy of the Moderna Vaccine, and individuals with these questions are being expelled from employment, school, transportation, and the military, the public has an urgent and immediate need to have access to this data. The value of this information will be all but useless to these individuals if they are forced to receive a vaccine prior to seeing the data relied upon by the FDA and the various institutions mandating approved vaccines. Without immediate access to the data, many of these individuals will forever lose the chance to evaluate the data for themselves and see whether this vaccine is indeed "safe and effective" prior to being mandated to receive it.

Having multiple trusted independent authorities, including PHMPT, review the safety and effectiveness data sought in this FOIA request will almost certainly assist these individuals in evaluating their vaccine decisions. For all of these reasons, PHMPT has demonstrated its request significantly concerns matters of current exigency to the American public. Therefore, the first factor in FOIA's "compelling need" analysis weighs heavily in favor of granting expedited processing.

(ii) Consequences in delaying a response would compromise significant recognized interests

With respect to the second factor in the "compelling need" analysis, the consequences of delaying a response to PHMPT's FOIA request would compromise significant recognized interests. As described above, the FDA's regulations recognize the public's interest in having aspects of the biological product file "immediately available for public disclosure." 21 C.F.R. § 601.51(e). The regulation specifically enables the public to see firsthand the safety and effectiveness data and information relating to the Moderna Vaccine. *Id*. This regulation, like many others that regulate public health and consumer products, is built on significant recognized

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[25] *See, e.g.*, https://www.nj.com/coronavirus/2021/08/murphy-orders-vaccination-requirement-for-all-nj-state-workers-including-at-public-colleges.html (last visited 02/19/2022).

[26] *See* New York bill A11179, available at https://www.nysenate.gov/legislation/bills/2019/A11179. *See generally* https://eastcountytoday.net/buffy-wicks-transportation-bill-could-become-california-vaccine-passport-bill/ (last visited 02/19/2022).

[27] https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/ (last visited 2/19/22).

[28] https://www.msn.com/en-us/news/us/biden-urges-private-companies-to-implement-covid-19-vaccine-requirements-following-Pfizer-e2-80-99s-fda-approval/ar-AANEcYs?ocid=uxbndlbing (last visited 02/19/2022). *See also* https://www.nytimes.com/2021/08/23/us/Pfizer-vaccine-mandates.html (noting that FDA approval of the Pfizer Vaccine "is opening the way for institutions like the military, corporate employers, hospitals and school districts to announce vaccine mandates for their employees") (last visited 02/19/2022); https://www.msn.com/en-us/news/us/now-that-a-covid-19-shot-is-fully-approved-employer-mandates-are-rolling-in-but-will-vaccination-rates-in-the-us-go-up/ar-AANGDTy?ocid=uxbndlbing (last visited 02/19/2022); https://news.yahoo.com/surgeon-general-vivek-murthy-says-205530053.html (quoting the Surgeon General referring to vaccine mandates as "reasonable") (last visited 02/19/2022).

interests, such as "informed consent" and "consumer protection." This fact is further demonstrated by FDA's mission statements published on its website: "[T]he mission of FDA is to enforce laws enacted by the U.S. Congress and regulation established by the agency to protect the consumer's health, safety, and pocketbook"[29]; "FDA is responsible for advancing the public health by . . . helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health."[30] Moreover, notions of informed consent have been codified in jurisdictions all across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent."[31]

A sense of trust is created when a product becomes licensed by the FDA, and therefore, as explained by Dr. Fauci, "a flood" of vaccine mandates follow FDA approval of a COVID-19 vaccine.[32] As anticipated, after the FDA's approval of Pfizer's COVID-19 vaccine, Comirnaty, President Biden actively encouraged "companies in the private sector to step up the vaccine requirements[.]"[33]

Additionally, Moderna has recently requested EUA for its vaccines for children[34] and these requests are based on data that relate to the clinical trials used for Spikevax. The requested data underlies the immunobridging that is now occurring in the trials for children 6 months through 17 years of age and would shed light on the efficacy of those vaccines. Parents across the country are currently being faced with the decision of whether or not to vaccinate their children, whether or not to administer a booster to their child, and, if so, to choose which vaccine to administer. In order to make an informed decision and to give informed consent, all of the relevant data should be disclosed in a timely manner. Otherwise, these parents will be unable to make a truly informed choice until that happens.

The combination of COVID-19 vaccine mandates, additional EUAs being granted for different age groups, and the lack of disclosure regarding the determination of the products safety

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[29] https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/fda-related-laws-regulations-and-guidances (last visited 03/16/22).

[30] https://www.fda.gov/about-fda/what-we-do (last visited 2/19/22).

[31] Tex. Civ. Prac. & Rem. Code § 74.101.

[32] https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/ (last visited 2/19/22).

[33] https://www.msn.com/en-us/news/us/biden-urges-private-companies-to-implement-covid-19-vaccine-requirements-following-Pfizer-e2-80-99s-fda-approval/ar-AANEcYs?ocid=uxbndlbing (last visited 02/19/2022). *See also* https://www.nytimes.com/2021/08/23/us/Pfizer-vaccine-mandates.html (noting that FDA approval of the Pfizer Vaccine "is opening the way for institutions like the military, corporate employers, hospitals and school districts to announce vaccine mandates for their employees") (last visited 02/19/2022); https://www.msn.com/en-us/news/us/now-that-a-covid-19-shot-is-fully-approved-employer-mandates-are-rolling-in-but-will-vaccination-rates-in-the-us-go-up/ar-AANGDTy?ocid=uxbndlbing (last visited 02/19/2022); https://news.yahoo.com/surgeon-general-vivek-murthy-says-205530053.html (quoting the Surgeon General referring to vaccine mandates as "reasonable") (last visited 02/19/2022).

[34] *See* https://www.cnn.com/2022/04/28/health/moderna-vaccine-eua-young-children/index.html and https://www.healio.com/news/primary-care/20220323/moderna-seeks-covid19-vaccine-authorization-for-kids-younger-than-6.

and effectiveness, violates the significant recognized interests of informed consent and consumer protection.

Without disclosure, consumers that are confronted with COVID-19 vaccine mandates are forced to choose between taking a vaccine without the science-based information necessary to make an informed decision, or losing their job, occupational benefits, access to medical procedures,[35] and access to educational opportunities.[36] Therefore, no matter a person's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the science-based information used to determine the Moderna Vaccine's safety and effectiveness compromises significant recognized interests: informed consent and consumer protection.

For the reasons set forth above, PHMPT has demonstrated that a delay of its FOIA request would compromise significant recognized interests. Thus, the second factor in FOIA's "compelling need" analysis weighs heavily in favor of granting expedited processing.

(iii) PHMPT's request concerns federal government activity

Finally, the information PHMPT seeks clearly concerns actual or alleged federal government activity for at least two reasons. First, the FDA, a federal agency, has a regulatory obligation to release aspects of the Moderna Vaccine's biological product file such that it is "immediately available for public disclosure" after a license has been issued. 21 C.F.R. § 601.51(e). Such aspects include all safety and effectiveness data and information. *Id*.

Second, and perhaps most importantly, PHMPT's request concerns whether the FDA approved the Moderna Vaccine based on adequate data and information. PHMPT requested information relating to the federal licensing of the Moderna Vaccine. This particular request significantly concerns the federal government's activity since the federal government was not only involved in the licensure of the Moderna Vaccine but, crucially, the federal government was also heavily involved in the vaccine's research and development. According to the National Institutes of Health's (NIH) website:

> [B]ecause of [the] work that NIH was already doing when the COVID-19 pandemic began, researchers were able to come up with a vaccine for this new virus much faster . . .Years before the COVID-19 pandemic began, experts at the NIH Vaccine Research Center (VRC) were studying coronaviruses to find out how to protect against them . . . The VRC worked with a company called Moderna to use this information to quickly customize their prototypes approach to the SARS-CoV-2 spike protein. By early February [2020], a COVID-19 vaccine candidate had been designed and manufactured. This Vaccine is called mRNA 1273 . . . *the NIH-*

[35] https://www.bbc.com/news/world-us-canada-60132765 (last visited 03/16/22); https://www.wsoctv.com/news/local/i-will-die-free- unvaccinated-burke-county-man-denied-kidney-transplant-by-hospital/OJGAFURR4FGERJB7VT24P5RED4/ (last visited 03/16/22); https://www.nbc11news.com/2021/10/08/colorado-hospital-denies-unvaccinated-patient-transplant/ (last visited 03/16/22); https://www.foxnews.com/us/uva-hospital-refused-unvaccinated-transplant (last visited 03/16/22); https://www.businessinsider.com/ohio-woman-liver-disease-denied-transplant-vaccine-cleveland-clinic-2021-10.

[36] *See* New York bill S6495, available at https://www.nysenate.gov/legislation/bills/2021/S6495 (last visited 02/19/2022).

Moderna vaccine was authorized by the U.S. Food and Drug Administration (FDA) for emergency use. (emphasis added)[37]

The federal government's activities in designing and manufacturing the "NIH-Moderna vaccine" is particularly important because federal employees that were a part of its development and therefore are potential co-owners of the patents involved in the Moderna Vaccine. *See* U.S. Application No. 62/972,886 & No. 16/344,774; *see also* Research Collaboration Agreement 2017-1179 & "Material Transfer Agreement" executed on 12/16/2019.[38] Moreover, under 15 U.S.C. § 3710c, which regulates the "Distribution of royalties received by Federal agencies," federal agencies and their employees are authorized to profit from the licensing and assignment of inventions, such as the Moderna Vaccine. The federal government has already spent $6 billion helping develop, test, and manufacture the "NIH-Moderna vaccine."[39] The combination of potential conflicts of interest within the federal government itself, and the large sums of taxpayer money spent to obtain the FDA's approval of the Moderna Vaccine, requires immediate transparency into the federal government's activities. Thus, the third factor in FOIA's "compelling need" analysis weighs heavily in favor of granting expedited processing.

PHMPT has demonstrated (i) the request concerns a matter of current exigency to the American public, (ii) the consequences of delaying a response would compromise a significant recognized interest, and (iii) the request concerns federal government activity. Therefore, PHMPT has reasonably established under FOIA a "compelling need" for the expedited processing of its request. 5 U.S.C. § 552(a)(6)(E)(v)(II)

C. Conclusion

Given the foregoing, ICAN hereby appeals and urges the FDA to grant its request for expedited processing within 20 days of this appeal. Thank you for your time and attention to this matter. If you require any additional information, please contact us at (212) 532-1091 or through email at foia@sirillp.com.

[37] https://covid19.nih.gov/news-and-stories/vaccine-development (last visited 03/16/22).

[38] https://www.citizen.org/article/the-nih-vaccine/#_ftn2 (last visited 03/16/22).

[39] https://www.statnews.com/2021/04/30/u-s-government-has-invested-6-billion-in-modernas-covid-19-vaccine/ (last visited 03/16/22).

Very truly yours,

/s/ Aaron Siri

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin Farnsworth, Esq.

Enclosures

Exhibit 1

Siri | Glimstad

NEW YORK | LOS ANGELES | MIAMI
PHOENIX | DETROIT | DENVER

200 Park Avenue, 17th Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL February 23, 2022

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: Moderna COVID-19 Vaccine Biological Product File (IR#0710)

Dear Sir or Madam:

This firm represents Public Health and Medical Professionals for Transparency ("**PHMPT**").

On January 31, 2022, the Food and Drug Administration ("**FDA**") approved the Moderna[1] COVID-19 Vaccine, marketed as Spikevax (the "**Moderna Vaccine**") for individuals 18 years of age and older. On behalf of PHMPT and its individual members, please provide the following records to foia@sirillp.com in electronic form:

> **All data and information for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e)[2] with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.[3]**

[1] For purposes of this request, Moderna shall be interpreted to include Moderna, Inc. and any of its parents, subsidiaries and affiliates.

[2] 21 C.F.R. § 601.51(e) provides that after a biological product is licensed, the following information shall be made available for immediate disclosure absent extraordinary circumstances: "(1) All safety and effectiveness data and information. (2) A protocol for a test or study . . . . (3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information . . . . (4) A list of all active ingredients and any inactive ingredients . . . . (5) An assay method or other analytical method . . . . (6) All correspondence and written summaries of oral discussions relating to the biological product file . . . . (7) All records showing the manufacturer's testing of a particular lot . . . . (8) All records showing the testing of and action on a particular lot by the [FDA]."

[3] For the avoidance of doubt, this request includes but is not limited to all of the data and information in the biological product file, as defined in 21 C.F.R. § 601.51(a), for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.

I. EXPEDITED PROCESSING REQUESTED

PHMPT requests expedited processing for this request as it meets the requirements for expedited processing under both FDA's FOIA Regulations as well as FOIA itself.

A. PHMPT Qualifies for Expedited Processing Under FOIA

FOIA provides for "expedited processing of requests for records" upon a showing of "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(I). The requestor shows a "compelling need" when it is "primarily engaged in disseminating information," and there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II).

Here, PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists. PHMPT exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines. PHMPT intends to make any records produced in response to this FOIA request immediately available to the public through both its website and its individual members' platforms. Many of PHMPT's individual members, including all its members that are journalists, are primarily engaged in disseminating information to the public and do so across various platforms, including through interviews, articles, blogs, essays, and podcasts. Therefore, PHMPT and many of its members are "primarily engaged in disseminating information [] to inform the public," and, as explained below, there is a clear "urgency to inform the public concerning actual or alleged Federal Government activity," which in this case is the data and information underlying the licensure of the Moderna Vaccine. Accordingly, expedited processing of this request under FOIA is warranted.

B. PHMPT Qualifies for Expedited Processing Under the FDA's FOIA Regulations

Notably, separate and apart from the FDA's obligation to comply with FOIA, it has an independent duty to inform the public concerning the data and information underlying a licensed vaccine. The FDA's Regulations expressly provide that "[a]fter a license has been issued, the following data and information in the biological product file are *immediately available* for public disclosure unless extraordinary circumstances are shown: (1) All safety and effectiveness data and information . . ." 21 C.F.R. § 601.51(e)(1) (emphasis added). Thus, the FDA's own regulations expressly recognize the importance of having the data and information relied upon to license a vaccine "immediately available for public disclosure." *Id.* This policy supports the FDA's claimed commitment to,[4] and assurances of, transparency[5] as a lack of transparency erodes the confidence the medical and scientific communities and the public have in the conclusions reached by the FDA. However, the fact that the FDA did not release the documents following licensure necessitated this FOIA request.

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[4] https://www.fda.gov/news-events/press-announcements/covid-19-update-fdas-ongoing-commitment-transparency-covid-19-euas (last visited 2/19/2022).

[5] https://www.fda.gov/about-fda/transparency/transparency-initiative (last visited 2/19/2022); https://www.fda.gov/news-events/speeches-fda-officials/fostering-transparency-improve-public-health (last visited 2/19/2022).

But aside from the FDA's duty to make immediately available the safety and effectiveness data of a licensed vaccine, the FDA's FOIA regulations anticipate scenarios where FOIA requests must be expedited. Specifically, a requestor is entitled to expedited processing where:

> (1) The requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;
>
> (2) There is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly; however, a news media publication or broadcast deadline alone does not qualify as an urgent need, nor does a request for historical information; and
>
> (3) The request for records specifically concerns identifiable operations or activities of the Federal Government.

21 C.F.R. § 20.44(c)(1)-(3).

PHMPT easily meets all three requirements. As noted above, PHMPT is an organization made up of public health professionals, medical professionals, scientists, and journalists that was created and exists for the sole purpose of disseminating to the public the data and information in the biological product files for each of the COVID-19 vaccines. Therefore, PHMPT is certainly "primarily engaged in disseminating information to the general public." 21 C.F.R. § 20.44(c)(1).

Next, there is plainly an urgent public need for transparency with regard to the data relied upon in licensing the Moderna Vaccine for at least two distinct reasons beyond the FDA's own regulations which admit the urgent need for transparency and disclosure of this information. As required by Congress, the FDA may only license vaccines that have been proven to be "safe and effective," *see, e.g.*, 21 U.S.C. § 393, and the FDA makes this determination based on, *inter alia*, clinical trial reports provided by the sponsor which must be sufficient to demonstrate the product is both "safe" and "effective."[6] 21 C.F.R. 601.2(a). There is, however, an ongoing, public national debate regarding the adequacy of the data and information, and analyses of same, relied upon by the FDA to license the COVID-19 vaccines, including the Moderna Vaccine. On the one hand, there are numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms that have declared that the data and information underlying the licensure of the Moderna Vaccine is more than sufficient for licensure. For example, in a statement released on January 31, 2022, acting FDA Commissioner Janet Woodcock, M.D., stated:

> The public can be assured that Spikevax meets the FDA's high standards for safety, effectiveness and manufacturing quality

[6] The FDA explains in its guidance materials that the clinical trials relied upon for approval are typically "1 to 4 years" (https://www.fda.gov/patients/drug-development-process/step-3-clinical-research) and the duration of clinical trials should "reflect the product and target condition." https://www.fda.gov/media/102332/download (last visited 02/19/2022). *See also* https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved (last visited 02/19/2022); https://www.fda.gov/about-fda/what-we-do (last visited 02/19/2022).

> required of any vaccine approved for use in the United States. While hundreds of millions of doses of Moderna COVID-19 Vaccine have been administered to individuals under emergency use authorization, we understand that for some individuals, FDA approval of this vaccine may instill additional confidence in making the decision to get vaccinated.[7]

Peter Marks, M.D., Ph.D., the director of FDA's Center for Biologics Evaluation and Research, made similar remarks:

> The FDA's medical and scientific experts conducted a thorough evaluation of the scientific data and information included in the application pertaining to the safety, effectiveness, and manufacturing quality of Spikevax. This includes the agency's independent verification of analyses submitted by the company, our own analyses of the data, along with a detailed assessment of the manufacturing processes, test methods and manufacturing facilities . . . Safe and effective vaccines are our best defense against the COVID-19 pandemic, including currently circulating variants. The public can be assured that this vaccine was approved in keeping with the FDA's rigorous scientific standards.[8]

Even prior to FDA approval of the Moderna Vaccine, government officials, public health authorities, and medical professionals repeatedly claimed that COVID-19 vaccines were "safe and effective."[9]

On the other hand, numerous public health officials, media outlets, journalists, scientists, politicians, public figures, and others with large social or media platforms have publicly raised questions regarding the sufficiency of the data and information, the adequacy of the review, and appropriateness of the analyses relied upon to license the Moderna Vaccine, including a number of the scientists and journalists that are members of PHMPT. For example, in July 2021, a group of 27 clinicians, scientists, and patient advocates, including PHMPT members Peter Doshi, Ph.D., Senior Editor for The BMJ and Associate Professor of Pharmaceutical Health Services Research at the University of Maryland School of Pharmacy,[10] and Peter A. McCullough, M.D. filed an amended Citizen Petition[11] with the FDA, claiming that the available evidence for licensure of the

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[7] https://www.cnn.com/2022/01/31/health/moderna-covid-vaccine-fda-approval/index.html.

[8] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine.

[9] *See, e.g.*, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html#:~:text=COVID%2D19%20vaccines%20are%20safe,vaccine%20as%20soon%20as%20possible. (last visited 02/19/2022). *See also* https://www.who.int/news-room/feature-stories/detail/vaccine-efficacy-effectiveness-and-protection ("COVID-19 vaccines have proven to be safe, effective and life-saving.") (last visited 02/19/2022); https://www.doh.wa.gov/Emergencies/COVID19/VaccineInformation/SafetyandEffectiveness ("COVID-19 vaccines are safe") (last visited 02/19/2022).

[10] https://www.bmj.com/about-bmj/editorial-staff/peter-doshi (last visited 02/19/2022).

[11] https://www.regulations.gov/document/FDA-2021-P-0521-0001 (last visited 02/19/2022).

Moderna Vaccine "is simply not mature enough at this point to adequately judge whether clinical benefits outweigh the risks in all populations."[12] Separately, Dr. Doshi has publicly questioned the lack of transparency regarding the vaccine approval process[13] which Dr. Peter Marks publicly disputed.[14] Aaron Kheriaty, M.D., former-Professor of Psychiatry at UCI School of Medicine, former-Director of the Medical Ethics Program at UCI Health,[15] and a member of PHMPT, has also questioned the FDA's approval process. For example, in an article published in the Wall Street Journal, Dr. Kheriaty questioned the need for student vaccination requirements based on, among other things, a review[16] by the FDA's Vaccines and Related Biological Products Advisory Committee that indicates a risk of heart inflammation after vaccination.[17] Government officials have raised similar concerns about the lack of transparency in the review process, arguing that it is "essential" for the FDA to, among other things, "make the data generated by clinical trials and supporting documents submitted to the FDA by developers available to the public."[18] PHMPT incorporates by reference, as if cited and fully set forth herein, any and all articles, media, and publications regarding or reflecting the public discussion, discourse, and debate regarding the Moderna Vaccine, including all matters related to the licensure of this product.

Given this widespread and ongoing public debate, the medical and scientific communities and the public have an immediate need to review the data and information underlying the licensure of the Moderna Vaccine. Public disclosure of this information will inform this ongoing public debate. Releasing this data should also confirm the FDA's conclusion and thus increase confidence in the safety and efficacy of the Moderna Vaccine.

Secondly, and perhaps even more significantly, there is an urgent need for the public to have immediate access to the data and information underlying the licensure of the Moderna Vaccine because, over the objections of many, this product is being mandated to individuals across

[12] *See* https://blogs.bmj.com/bmj/2021/06/08/why-we-petitioned-the-fda-to-refrain-from-fully-approving-any-covid-19-vaccine-this-year/ (last visited 02/19/2022).

[13] *See* https://blogs.bmj.com/bmj/2021/08/23/does-the-fda-think-these-data-justify-the-first-full-approval-of-a-covid-19-vaccine/ (last visited 2/19/2022); https://blogs.bmj.com/bmj/2021/01/04/peter-doshi-Pfizer-and-modernas-95-effective-vaccines-we-need-more-details-and-the-raw-data/ (last visited 2/19/2022); https://blogs.bmj.com/bmj/2020/11/26/peter-doshi-Pfizer-and-modernas-95-effective-vaccines-lets-be-cautious-and-first-see-the-full-data/ (last visited 02/19/2022).

[14] https://www.statnews.com/2020/12/17/did-the-fda-understaff-its-review-of-the-Pfizer-biontech-vaccine/ (last visited 02/19/2022).

[15] https://www.aaronkheriaty.com/bio (last visited 02/19/2022).

[16] https://www.fda.gov/media/150054/download (last visited 02/19/2022)

[17] https://www.wsj.com/articles/university-vaccine-mandates-violate-medical-ethics-11623689220 (last visited 02/19/2022).

[18] https://www.warren.senate.gov/imo/media/doc/2020.09.14%20Letter%20to%20FDA%20re%20transparency%20in%20vaccine%20review%20process_.pdf (last visited 02/19/2022).

the country by the federal government,[19] local governments, [20] public and private employers,[21] universities, [22] schools,[23] and various other institutions,[24] and many are expected to follow suit. At the federal level, legislation was introduced that would require COVID-19 vaccines for air travel into or out of the United States,[25] and the Pentagon has mandated the COVID-19 vaccines

[19] *See, e.g.*, https://www.natlawreview.com/article/covid-19-vaccine-added-to-requirements-green-card-processing-effective-oct-1 (last visited 02/19/2022); https://apnews.com/article/business-health-coronavirus-pandemic-coronavirus-vaccine-4cf7451267919302de4a7b591508e80c (last visited 02/19/2022); https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF (last visited 2/19/2022); https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/29/fact-sheet-president-biden-to-announce-new-actions-to-get-more-americans-vaccinated-and-slow-the-spread-of-the-delta-variant/ (last visited 02/19/2022).

[20] *See, e.g.*, https://www.cnn.com/2021/08/12/us/san-francisco-vaccine-requirement/index.html (last visited 02/19/2022); https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page (last visited 2/19/2022); https://news.yahoo.com/orleans-now-requires-proof-vaccination-230433492.html (last visited 02/19/2022).

[21] *See, e.g.*, https://www.cnbc.com/2021/08/06/united-airlines-vaccine-mandate-employees.html (last visited 02/19/2022); https://sanfrancisco.cbslocal.com/2021/08/02/covid-kaiser-permanente-makes-vaccination-mandatory-for-all-employees/ (last visited 2/19/2022); https://abcnews.go.com/Health/wireStory/walmart-mandates-vaccines-workers-headquarters-79177220 (last visited 02/19/2022); https://www.kpbs.org/news/2021/aug/17/encinitas-covid-19-vaccine-negative-test-employees/ (last visited 02/19/2022); https://www.cnbc.com/2021/08/09/covid-vaccine-mandates-sweep-across-corporate-america-as-delta-surges.html (last visited 2/19/2022); https://www.reuters.com/business/energy/chevron-begins-covid-19-vaccination-mandates-wsj-2021-08-23/ (last visited 02/19/2022); https://thehill.com/policy/healthcare/569051-Pfizers-full-approval-triggers-new-vaccine-mandates (last visited 02/19/2022); https://cvshealth.com/news-and-insights/statements/cvs-health-will-require-covid-19-vaccinations-for-clinical-and-corporate-employees (last visited 02/19/2022).

[22] *See* (last visited 02/19/2022). *See also, e.g.*, https://www.nbcnews.com/health/health-news/colleges-universities-covid-vaccination-mandates-facing-pushback-n1273916 (last visited 02/19/2022); https://www.colorado.edu/covid-19-updates/covid-19-vaccination (last visited 02/19/2022); https://uhs.berkeley.edu/requirements/covid19 (last visited 02/19/2022); https://huhs.harvard.edu/covid-19-vaccine-requirement-faqs (last visited 02/19/2022); https://www2.gmu.edu/safe-return-campus/vaccination-requirements (last visited 2/07/2022).

[23] *See, e.g.*, https://www.npr.org/sections/back-to-school-live-updates/2021/08/20/1029837338/a-california-school-district-mandates-vaccines-for-eligible-students (last visited 2/19/2022); https://patch.com/massachusetts/salem/salem-school-committee-approves-vaccine-mandate-sports-band (last visited 2/19/2022); https://www.nbcnewyork.com/news/coronavirus/nyc-will-require-vaccination-for-high-risk-school-sports/3232745/ (last visited 02/19/2022); https://www.nj.com/hudson/2021/08/hoboken-believed-to-be-first-in-state-to-issue-mandate-for-students-12-and-up-get-vaccine-or-face-weekly-testing.html (last visited 02/19/2022); https://www.mercurynews.com/2021/08/19/la-county-school-district-mandates-covid-vaccines-for-k12-kids-others-soon-may-follow/ (last visited 02/19/2022).

[24] *See, e.g.*, https://www.reuters.com/world/us/new-york-city-mandates-covid-19-vaccine-public-school-teachers-staff-mayor-2021-08-23/ (last visited 02/19/2022); https://www.cbsnews.com/news/california-covid-vaccine-teachers-mandate/ (last visited 02/19/2022); https://www.nytimes.com/2021/08/18/us/washington-state-teacher-vaccine-mandate.html (last visited 02/19/2022); https://www.governor.ny.gov/news/governor-cuomo-announces-covid-19-vaccination-mandate-healthcare-workers (last visited 02/19/2022); https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx (last visited 02/19/2022); https://www.nytimes.com/2021/08/09/us/washington-state-workers-vaccine-mandate.html (last visited 02/19/2022); https://www.denvergov.org/Government/COVID-19-Information/Public-Health-Orders-Response/News-Updates/2021/Mayor-Hancock-Announces-COVID-19-Vaccine-Requirement-for-Employees (last visited 2/19/2022); *See* https://www.bostonherald.com/2021/08/19/baker-issues-vaccine-mandate-for-42000-state-employees/ (last visited 02/19/2022).

[25] https://www.congress.gov/bill/117th-congress/house-bill/4980?q=%7B%22search%22:%5b%224980%252 (last visited 02/19/2022).

for all military personnel.[26] At the state level, legislation has been introduced to require COVID-19 vaccines for all post-secondary students,[27] all state employees, [28] and even for all citizens of various states.[29] As explained by Dr. Anthony Fauci, "a flood" of vaccine mandates follow FDA approval of a COVID-19 vaccine,[30] and President Biden has actively encouraged "companies in the private sector to step up the vaccine requirements[.]"[31] During a time when COVID-19 vaccine mandates are being implemented over the objection of those that have questions about the data and information supporting the safety and efficacy of the Moderna Vaccine, and individuals with these questions are being expelled from employment, school, transportation, and the military, the public has an urgent and immediate need to have access to this data. The value of this information will be all but useless to these individuals if they are forced to receive a vaccine prior to seeing the data relied upon by the FDA and various institutions mandating approved vaccines. Without immediate access to the data, many of these individuals will forever lose the chance to evaluate the data for themselves and see whether this vaccine is indeed "safe and effective" prior to being mandated to receive it. Having multiple trusted independent authorities, including PHMPT, review the safety and effectiveness data sought in this FOIA request will almost certainly assist these individuals in evaluating their vaccine decisions. Therefore, for all of these reasons, PHMPT has shown there is "an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly." 21 C.F.R. § 20.44(c)(2).

Finally, PHMPT's request meets the third requirement for expedited processing – that "[t]he request for records specifically concerns identifiable operations or activities of the Federal Government." 21 C.F.R. § 20.44(c)(3). Here, PHMPT's records request specifically concerns identifiable activities—i.e., approval of the Moderna Vaccine—by the Federal Government—to wit, the FDA.

In light of the above, PHMPT has demonstrated that its request qualifies for expedited processing under both the FDA's FOIA regulations, as well as FOIA itself. PHMPT incorporates by reference, as if cited and fully set forth herein, any and all articles, media, and publications

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[26] https://thehill.com/policy/defense/568996-pentagon-to-mandate-covid-19-vaccine-for-military (last visited 02/19/2022).

[27] *See* New York bill S6495, available at https://www.nysenate.gov/legislation/bills/2021/S6495 (last visited 02/19/2022).

[28] *See, e.g.*, https://www.nj.com/coronavirus/2021/08/murphy-orders-vaccination-requirement-for-all-nj-state-workers-including-at-public-colleges.html (last visited 02/19/2022).

[29] *See* New York bill A11179, available at https://www.nysenate.gov/legislation/bills/2019/A11179. *See generally* https://eastcountytoday.net/buffy-wicks-transportation-bill-could-become-california-vaccine-passport-bill/ (last visited 02/19/2022).

[30] https://www.usatoday.com/story/news/health/2021/08/06/anthony-fauci-covid-vaccine-mandates-fda-full-approval/5513121001/ (last visited 2/19/22).

[31] https://www.msn.com/en-us/news/us/biden-urges-private-companies-to-implement-covid-19-vaccine-requirements-following-Pfizer-e2-80-99s-fda-approval/ar-AANEcYs?ocid=uxbndlbing (last visited 02/19/2022). *See also* https://www.nytimes.com/2021/08/23/us/Pfizer-vaccine-mandates.html (noting that FDA approval of the Pfizer Vaccine "is opening the way for institutions like the military, corporate employers, hospitals and school districts to announce vaccine mandates for their employees") (last visited 02/19/2022); https://www.msn.com/en-us/news/us/now-that-a-covid-19-shot-is-fully-approved-employer-mandates-are-rolling-in-but-will-vaccination-rates-in-the-us-go-up/ar-AANGDTy?ocid=uxbndlbing (last visited 02/19/2022); https://news.yahoo.com/surgeon-general-vivek-murthy-says-205530053.html (quoting the Surgeon General referring to vaccine mandates as "reasonable") (last visited 02/19/2022).

regarding or reflecting the public discussion, discourse, and debate regarding the mandating or potential mandating of the Moderna Vaccine. PHMPT certifies that the information in this request is true and correct to the best of its knowledge and belief.

II. FEE WAIVER REQUEST

PHMPT is a nonprofit and asks that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii) on the basis that "disclosure of the [requested] information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government[.]" Specifically, disclosure of the requested information will immediately address the ongoing public debate about the safety and efficacy of the Moderna Vaccine and the clinical trials underlying the FDA's approval of same. The information PHMPT requests will not contribute to any commercial activities.

Note that in the event only a portion or portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable or can be deidentified. We further request that you describe any redacted, deleted, or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. PHMPT reserves all rights to appeal the withholding or deletion of any information.

A determination regarding expedited processing should be made within ten (10) days. Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and PHMPT may immediately file an administrative appeal or an action.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact Aaron Siri at (212) 532-1091 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin Farnsworth, Esq.

Exhibit 2

U.S. FOOD & DRUG ADMINISTRATION

March 01, 2022

In Reply refer to
FOIA Control #:
2022-1614

Requester reference:
IR#0710

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY
PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY
200 PARK AVE FL 17
17th Floor
New York NY 10166 US

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

All data and information for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System. See letter for further details.

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Wilson M. Russ, Freedom Of Information Specialist, at (301) 796-8981 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

Office of Government Information Services
National Archives and Administration
8601 Adelphi Road – OGIS
College Park, MD 20740-6001
Telephone:202-741-5770
Toll-Free: 1-877-684-6448
Email:ogis@nara.gov
Fax: 202-741-5769

and/or

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food Administration
5630 Fishers Lane, Room 1050
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director

Exhibit 3

U.S. FOOD & DRUG ADMINISTRATION

March 07, 2022

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY
PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY
200 PARK AVE FL 17
17th Floor
New York NY 10166 US

In Reply refer to
FOIA Control #:
2022-1614

Requester reference:
IR#0710

Dear Requester:

This is in reference to your request(s) for record(s) from the Food and Drug Administration (FDA) pursuant to the Freedom of Information Act (FOIA).

All data and information for the Moderna Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System. See letter for further details.

The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."

I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing. The responding agency office will process your request in the order in which it was received.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision. Your appeal must be mailed within 90 days from the date of this response, to: Director, Office of the Executive Secretariat, US Food & Drug Administration, 5630 Fishers Lane, Room 1050, Rockville, MD 20857, E-mail: FDAFOIA@fda.hhs.gov. Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

You may also contact the FDA FOIA Public Liaison, Office of the Executive Secretariat, 5630 Fishers Lane, Room 1050, Rockville, MD 20857; email: FDAFOIA@fda.hhs.gov.

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road–OGIS, College Park, MD 20740-6001, Telephone: 202-741-5770, Toll-Free: 1-877-684-6448, E-mail: ogis@nara.gov, Fax: 202-741-5769.

Sincerely,

SARAH KOTLER
Director